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Inspections, Human Medicines Pharmacovigilance and Committees Division

CAT monthly report of application procedures, guidelines and related documents on advanced therapies

July 2017 meeting

The Committee for Advanced Therapies (CAT) held its 95th CAT meeting on 12 – 14 July 2017.

The CAT Monthly Report includes statistical data on CAT scientific recommendations on Advanced Therapy Medicinal Product (ATMP) classification, certifications, initial evaluations, CAT contributions to Scientific Advice and Paediatric Investigation Plans, as well as variations, line extensions, renewals.

Scientific recommendation on advanced therapy product classification

Further to consultation with the European Commission, the CAT finalised 4 scientific recommendations on the classification of advanced therapy medicinal products.

The following products were classified as somatic cell therapy medicinal products:

- Autologous uncultured cells of stromal vascular fraction intended for the relief of symptoms of osteoarthritis.
- Human umbilical cord blood-derived mesenchymal stem cells intended for the treatment of atopic dermatitis.

The following products were classified as tissue engineered products:

- Autologous keratinocytes intended for the treatment of burns and chronic, severe wounds.
- Autologous chondrocytes intended for the repair of single symptomatic cartilage defects of the knee.

Organisational matters

- CAT adopted the concept paper on the revision of the guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells. The document will be published shortly.
- CAT finalised the programme of the Expert Meeting on adeno-associated viral (AAV) vectors that will take place on 6 September 2017. This meeting is not open to the public.

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- CAT discussed the preparation of the Expert meeting on genome editing that will take place on 18 October 2017. This meeting is organised jointly by CAT and the CHMP Pharmacogenomics Working Party (PGWP). CAT and PGWP members will discuss with experts from academia and industry the state of art in genome editing technologies, the current product developments and the potential consequences on existing EMA guidance. This meeting is not open to the public.

New ATMP related documents published on the EMA Website

- Development of non-substantially manipulated cell-based ATMPs: flexibility introduced via the application of the risk-based approach
- GLP requirement for ATMPs

Overview of product-related activities

The Committee discussed ongoing evaluation procedures for ATMPs and other related procedures as summarised in the following tables:

Initial Evaluation of Marketing Authorisation Applications (MAA) for ATMP										
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Submitted MAAs	3	1	2	3	2	2	1	1	1	16
Positive draft Opinion	1	0	1[ii]	1[ii]	2	1	1	2	1	10*
Negative draft opinions	1[i]	0	1[ii]	0	0	0	2[iii]	0	0	4
Withdrawals	1	1[i]	0	0	2	0	0	0	0	4
Ongoing MAAs										2

*** Corresponding to 9 ATMPs**
[i] Same product (Cerepro)
[ii] Same product (Glybera)
[iii] CAT adopted two negative draft opinions for the same product (Heparesc)

Variations (Type II) for authorised ATMP										
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Positive Opinion	0	0	1	1	9	4	3	6	3	27

Scientific recommendation on advanced therapy classification										
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Submitted	22	19	12	22	20	28	61	60	28	272
Adopted	12	27	12	16	23	29	31	87	34	271

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs										
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Submitted	1	0	0	1	3	1	1	2	1	10
Adopted	0	1	0	1	1	2	1	1	3	10

Scientific advice procedure for ATMPs										
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Number of procedures	17	19	21	19	23	33	39	46	27	244

Paediatric Investigation Plans (PIP) for ATMPs										
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**Total**
Number of procedures	3	4	4	8	5	4	3	5	1	37

Prime Eligibility for ATMPs									
	2016	**2017**							**Total**
Discussed	22	13							35
Granted	8	4							12

Upcoming meetings following the July 2017 CAT meeting

The 96th meeting of the CAT will be held on 6 – 8 September 2017.

NOTE:

1. This Monthly Report, the Agenda of this meeting, the Minutes of the previous CAT meeting and other documents can be found on the internet at the following location: European Medicines Agency - Committee meeting reports - CAT: Committee meeting reports
2. Specific information related to ATMPs and the activities of the CAT (role, responsibilities and composition) can be found at: European Medicines Agency - CAT - Committee for Advanced Therapies (CAT)

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